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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,217

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EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,217	<b>Applicant(s)</b> SHIMIZU ET AL.	
	<b>Examiner</b> RUIXIANG LI	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4,6-8,10-17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) 4,6-8 and 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17 and 19-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of Application, Amendments, and/or Claims**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/12/2008 has been entered. Claim 18 is canceled. Claim 18 is amended. Claims 19-21 are added. Claims 4, 6-8, 10-17, and 19-21 are pending. Claims 17 and 19-21 are under consideration. All other claims are withdrawn from consideration.

### **Comments with Respect to Lack of Unity**

Applicants argue that the USPTO withdrew claims 4 and 6-16 from consideration without explanation in the office action mailed on 05/16/2008. Applicants argue that Applicant has added the special technical feature of the examinable group (claims 17 and 18)—inhibitors of p2ydependent LPA activity) to all independent claims (4, 10, and 16) to allow their rejoinder.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. The group being examined (claims 17 and 19-21) is drawn to a method of screening for an agonist or an antagonist to the LPA receptor comprising

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determining an effect of a test sample on the binding of LPA to p2y9. None of the other claims share this technical feature. Thus, group being examined (claims 17 and 19-21) and other groups of claims are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Thus, unity of invention is lacking and restriction is appropriate.

### **Withdrawn Objections and/or Rejections**

The rejection of claim 17 under 35 U.S.C. 102(b) as being by anticipated by Sathe et al. (US 6,010,877, Jan. 4, 2000) is withdrawn in view of amended claim.

The rejection of claims 17 and 18 under 35 U.S.C. §112, second paragraph is withdrawn in view of amended claim 17 and canceled claim 18.

### **Claim Rejections—35 USC § 112, 1<sup>st</sup> paragraph**

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 17 and 19-21 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

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To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 17 and 19-21 are drawn to a method of screening a candidate compound in test samples that enhance or inhibit p2y9 dependent LPA activity, comprising monitoring binding of the test samples to G protein-coupled protein p2y9, wherein the p2y9 protein comprises an amino acid sequence having a sequence identity of more than 95% to SEQ ID NO: 1. The claims encompass a genus of p2y9 protein variants. However, the claims do not require that the p2y9 proteins possess any particular any particular conserved structure or biological functions.

The instant disclosure of the p2y9 protein of SEQ ID NO: 1 does not adequately support the scope of the recited genus, which encompasses a substantial variety of homologues or variants of the p2y9 proteins. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). While disclosing the amino acid sequences of

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SEQ ID NO: 1 and its ligand, the instant disclosure fails to provide sufficient description information, such as definitive structural of the recited genus of p2y9 protein variants. There is no description of the conserved regions that are critical to the function of the genus recited. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. While the prior art teaches the amino acid sequence of SEQ ID NO: 1 (see, e.g., Sathe et al., US Patent No. 6,010,877), it does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed p2y9 proteins or a mutant thereof.

Due to the breadth of the recited genus and lack of the definitive structural and functional features of the recited genus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of p2y9 protein variants and thus the instantly claimed methods.

(iii). Response to Applicants' argument

Applicants argue that a large variety of alternative sequences of the recited protein species is presented within the specification as filed. Applicants argue that Applicant has incorporated 24 well known, reviewed and accepted scientific papers that teach a variety of protein species within this genus. Applicants argue that Applicant has found that the members within this art defined genus (less than 5% sequence structural primary sequence variability) respond by binding to lysophospholipid. Applicants also

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argue that applicant provides the examiner with a number of amino acid sequences of p2y9 from a variety of alleles were known before the filing of the present application as schedule A of this response.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the specification merely discloses the human p2y9 protein of SEQ ID NO: 1, but fails to disclose any other p2y9 protein variants. Secondly, the sequence search and prior art search do not reveal a genus of p2y9 proteins that bind lysophospholipid. Thirdly, while the Appendix C submitted on 02/14/2008 shows comparison of six amino acid sequences and shared homology among the six sequences, they do not provide evidence showing that Applicants were in possession of the recited genus of p2y9 proteins that bind to lysophospholipid at the time the application was filed.

#### **Claim Rejections under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph**

(i). The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 17 and 19-21 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 17 is indefinite because the preamble of the claim recites a method of screening a candidate compound in test samples that enhance or inhibit p2y9 dependent LPA dependent LPA activity. However, the claim does not set forth steps with respect to how to screen such a candidate compound and how to select a candidate compound that enhances or inhibits p2y9 dependent LPA activity. Claims 19-21 are rejected as dependent claims from claim 17. It is noted that

### **Conclusion**

No claims are allowed.

### **Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For



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more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/

Primary Examiner, Art Unit 1646

November 2, 2008